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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/620,278 | 07/15/2003 | Barrett R. Harvey | UTXB:715US | 4200 |

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EXAMINER

FORD, VANESSA L

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| ART UNIT | PAPER NUMBER |
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1645

DATE MAILED: 05/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 10/620,278 | Applicant(s) HARVEY ET AL. | |
| | Examiner Vanessa L. Ford | Art Unit 1645 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 March 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-48 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-48 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This Action is responsive to Applicants amendment and remarks filed March 7, 2005. Claims 1, 3 and 43 have been amended. Applicant's submission of a Declaration under 37 C.F.R.1. 132 and Appendix A (Titles of Scientific articles) are acknowledged.

2. The text of those sections of the Title 35, U.S. code not included in this action can be found in the prior Office Action.

Rejections Withdrawn

3. In view of Applicant's amendment and response the following rejections are withdrawn:

a) rejection of claims 1 and 3 under 35 U.S.C. 112, second paragraph, page 3, paragraph 4 of the previous Office action.

b) rejection of claim 22 under 35 U.S.C. 112, second paragraph, page 4, paragraph 5 as is withdrawn as it relates to the phrase "synthetic molecule". It should be remembered that the rejection under 35 U.S.C. 112, second paragraph for the phrase "small molecule" is maintained. See paragraph 4 below.

c) rejection of claims 1-41 and 43-48 under 35 U.S.C. 102(b), pages 6-8, paragraph 7 of the previous Office action.

d) rejection of claims 1-48 under 35 U.S.C. 103(a), pages 9-12, paragraph 8 of the previous Office action.

Rejections Maintained

4. The rejection under 35 U.S.C. 112, second paragraph is maintained for claims 1-48 for the reasons set forth on page 4, paragraph 5 of the previous Office Action.

The rejection was on the grounds that the claims are rejected under 35 USC 112 second paragraph for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The rejection was on the grounds that the claim recites the term "small molecule". It is unclear as to what the applicant is referring? Thus, the metes and bounds of "small molecule" are not disclosed in the instant specification and therefore cannot be ascertained. Clarification as to the meaning of these terms is required.

Applicant urges that a skilled practitioner would know the meaning of "small molecule". Applicant refers to a Declaration of filed under 37 C.F.R.1. 132 and Appendix A (Titles of scientific articles that use the phrase "small molecule" obtained from non-patented literature) to support their position.

Applicant's arguments filed March 7, 2005 have been fully considered but they are not persuasive. It is the Examiner's position that the phrase "small molecule" is a relative term and the metes and bounds of this term cannot be ascertained by the instant disclosure. To address Applicant's comments regarding Appendix A, it appears that this is a list of scientific articles that recite the phrase "small molecule". However, there is no defined molecular weight range found in the instant specification or Appendix A that would have led the skilled practitioner to the meaning of the phrase "small molecule".

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To address comments regarding the declaration submitted under 37 C.F.R. 1.132, it appears that this is an opinion declaration. The declaration discloses that the term "small molecule" describes "low molecular weight". The phrase "low molecular weight" is relative. For example, in comparison to 10,000 kDa, 1000 Kda appears small or low in molecular weight. Therefore, this rejection is maintained.

5. The rejection under 35 U.S.C. 102(e) as anticipated by Hultgren et al is maintained for claims 1, 4-9, 13-15, 17-24 and 34-35 for the reasons set forth on pages 4-6, paragraph 6 of the previous Office Action.

The rejection was on the grounds Hultgren et al teach a method for identifying a potentially therapeutically useful substance capable of interacting with a periplasmic molecular chaperone thereby preventing or inhibiting the interaction between a periplasmic molecular chaperone and a pilus subunit (column 10). Hultgren et al teach that the periplasmic chaperone or analogue thereof is in solubilized form (column 10). Hultgren et al teach that the measurement of the degree of binding can be determined *in vitro* by methods such as microcolormetric, radioimmunoassays and enzyme based assays (column 6). Hultgren et al teach that in instances wherein labeled substances, chaperones or antibodies are used, the label could be a radioactive label, a fluorescent or light absorbing label, an enzyme such as horseradish peroxidase, a ligand such as biotin or any other conventional labeling system known those skilled in the art (column 12). Hultgren et al teach that the binding between chaperones and pilus subunits are obtained by the interaction between the PapD chaperone in *E. coli*. (column 8). Since the interaction between the chaperones and pilus subunits takes place in the periplasmic space the nucleic acid sequences encoding the chaperones would be inherent in the teachings of the prior art.

Since the Office does not have the facilities for examining and comparing applicant's method with the method of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed method and the method of the prior art (i.e., that the method of the prior art does not possess the same material method steps and parameters of the claimed method). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

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Applicant urges that Hultgren et al do not teach contacting the bacterium with a labeled ligand. Applicant teach that Hultgren et al teach isolated protein with an unlabeled ligand and but not the contacting the bacterium with a labeled ligand. Applicant urges that Hultgren et al uses a "fluorescence labeled variant". Applicant urges that the prior art reference does not teach or disclose containing a bacterium with a labeled variant. Applicant urges that the Hultgren et al teach contacting the bacteria with a substance and the Hultgren et al do not teach that the substance is a labeled ligand. Applicant urges that Hultgren et al fail to teach selection of bacteria based on the presence of said labeled ligand in the periplasm. Applicant urges that Hultgren et al would not suggest or motivate one with skill in the art to select a bacterium as recited in step (c) of the claimed method. Applicant urges that Hultgren et al do not anticipate the claimed method.

Applicant's arguments filed March 7, 2005 have been fully considered but they are not persuasive. Hultgren et al teach a method of obtaining a bacterium as recited in the claimed method. Hultgren et al accomplishes this method step by the interaction of a molecular (periplasmic) chaperone with a binding site which is involved in the binding of pilus subunits during transport of these pilus subunits through the periplasmic space (column 8). Therefore, the prior art teaches that the method takes place in the periplasmic space of a bacterium. Hultgren et al teach that the periplasmic chaperone being bound to the pilus subunit may be labeled by means of an labeled ligand (column 11-12). Thus, the Examiner disagrees with Applicant's assertion that Hultgren et al do not teach "contacting the bacterium with a labeled ligand". Hultgren et al teach that

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bacterium are selected based on the periplasmic chaperone/pilus subunit binding interactions (columns 12-14). Therefore, the claimed method step of selecting a bacterium is taught by the prior art. To address Applicant's comment's regarding contacting the bacterium with a substance, it should be noted that Hultgren et al teach that the substance used to contact the bacteria can be "any compound" which interacts with the periplasmic chaperone and pilus subunits (column 7). Therefore, labeled ligands are not excluded from this genus of compounds. To address Applicant's comments regarding "fluorescence labeled variant", it should be noted that the fluorescence labeled variants used in the assay of the prior art are used to determine the interaction the periplasmic chaperone and the substance. To address Applicant's comments regarding motivation or suggest to one of skill in the art to select a bacterium used in the claimed method, it should be remembered that the art rejection is made under 35 U.S.C. 102, therefore the method of the prior art is the same as the claimed method. Applicant has provided no side-by-side comparison to show that the claimed method differs from that of the prior art. Therefore, it is the position of the Examiner that Hultgren et al anticipate the claimed invention.

New Ground of Rejection

Obviousness Type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 1-38 and 43-48 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-2 and 4-32 of copending Application No. 09/699, 023. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to a method of obtaining a bacterium comprising a nucleic acid sequence encoding a binding protein that are capable of a target ligand comprising the steps of: (a) providing a gram-negative bacterium comprising a nucleic acid sequence encoding a candidate binding protein, wherein said binding protein is expressed in the periplasm of said bacterium, (b) contacting said bacterium with a labeled ligand and (c) selecting said bacterium based on the presence of said labeled ligand wherein said

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ligand and said candidate binding protein are bound in said bacterium. The claimed method in application 09/699, 023 encompasses a genus of bacteria comprising nucleic acid sequences encoding a binding protein that are capable of a target ligand and this application (10/620,278) encompasses a particular species of bacteria comprising nucleic acid sequence encoding a binding protein having specific affinity for a target ligand. The method claimed in this application would be encompassed in the scope of the method claimed in co-pending application 09/699,023. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Status of Claims

7. No claims allowed.

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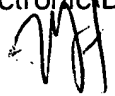
Conclusion

8. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (703) 872-9306.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (571) 272-0857. The examiner can normally be reached on Monday – Friday from 9:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (571) 272-0864.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov/>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


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May 9, 2005


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